OBJECTIVES: Foot ulceration is a major cause of disability in diabetes. The aim of this study was to estimate influence of severity of diabetic foot ulceration on HRQoL. **METHODS:** A survey among DFS (Diabetic Foot Syndrome) patients with active foot ulceration treated in ambulatory care was conducted. The PEDIS scale was used to classify severity of ulceration. To assess the impact of diabetic ulceration on HRQoL in DFS patients the EQ-5D-3L questionnaire was used. Utility scores were calculated based on Polish EQ-5D value set (Golicki et al.) **RESULTS:** Between April 2012 and May 2013 185 patients were questioned directly. 179 of them (131 males) completed the EQ-5D questionnaire and had full record on ulceration severity (the PEDIS scale). The mean age of patients was 61.9±10.6 years. Diabetes type 2 was diagnosed in 150 (83.8%) patients while diabetes type 1 in 26 (14.5%). Other type of diabetes was diagnosed in 2 persons and data on one were missing. Mean time from the diagnosis of diabetes was 18.0±11.1 years. 99 (55%) and 69 (39%) patients had grade 1 and 2 perfusion, respectively. The mean ulceration size was 6.2±13.4 cm^2. 74 (41.3%), 65 (36.3%) and 40 (22.3%) patients had grade 1, 2 and 3 depth/tissue loss respectively. 84 (46.9%), 55 (30.7%) and 36 (20.1%) patients had grade 1, 2 and 3 infection, respectively. Most patients (89.4%) had loss of protective sensation (grade 2 sensation). Mean utility value in overall population was estimated at 0.618±0.320. Very week negative correlation was found between ulceration size and utility value. Despite some differences in utility value in patients with different perfusion grade no strict correlations between severity of ulceration and utility values were found. **CONCLUSIONS:** There is little or no strict correlation between severity of ulceration measured with the PEDIS scale and HRQoL measured with the EQ-5D.

PDB85

DIABETIC PATIENTS IN PRIMARY CARE: SELF-PERCEPTION AND SATISFACTION. COMPARATIVE STUDY SPAIN VERSUS EUROPE

Sánchez-Piedra C, García-Pérez S, Sarría Santamera A
Agencia de Evaluación de Tecnologías Sanitarias (AETS), Madrid, Spain

OBJECTIVES: EUprimecare is an European Union project aimed at analyzing the costs and quality of the different models of primary care (PC) in Europe. The aim of this study is to analyze the management of diabetic patients in PC services in Spain compared to other European countries, the satisfaction of these patients with PC services and their self-perceived health status. **METHODS:** We conducted a population survey by telephone among PC users in each of the consortium countries (Germany, Spain, Estonia, Finland, Hungary, Italy and Lithuania). The questionnaire included information on sociodemographic characteristics, health status, satisfaction, utilization of PC services, and frequency of some interventions carried out by PC professionals. The survey was conducted to 431-432 PC users in each country (Ntotal = 3020). **RESULTS:** The percentage of diabetic patients in Spain was 6.7% (N = 29), lower than the overall average (9.1%). Eighty three percent of patients living in Spain were diagnosed by their PC physicians compared with 73% of the European average. Eighty six percent of patients in Spain said that they were being treated for diabetes (EU average = 84%) and in 88% of these cases the treatment was prescribed by their PC doctor (EU average = 70%). Only 6.9% of patients said their health was poor or very poor, the lowest proportion of all countries assessed. The overall satisfaction with PC services among diabetic patients was 4.10 points on a scale of 1 to 5. Satisfaction in Spain was below the global average for all the items measured. **CONCLUSIONS:** Diabetic patients in Spain are more frequently controlled by PC professionals than in other European countries. These patients have a better self-perceived health status and the results of this study suggest a lower level of dissatisfaction with the services provided by PC.

PDB86

PATIENTS PREFERENCES REGARDING THE TREATMENT OF TYPE II DIABETES MELLITUS: COMPARISON OF BEST-WORST SCALING AND ANALYTIC HIERARCHY PROCESS

Mühlbacher AC, Bethge S, Kaczynski A, Juhnke C
Hochschule Neubrandenburg, Neubrandenburg, Germany

OBJECTIVES: There is limited evidence available regarding patient preferences for treatment alternatives, including those treatment characteristics that have greatest influence on the perceived value, and how this knowledge can be used in health care decision-making. The objective of this study was to identify and elicit patient preferences for treatments in Type-II-Diabetes in different patient groups. **METHODS:** In order to elicit patient preferences this study used an explorative qualitative approach in combination with quantitative survey techniques. Literature research and semi-structured interviews (N=15) were the basis of quantitative elicitations (N=388) using Analytic-Hierarchy-Process (AHP) and Best-Worst-Scaling (BWS). The study aimed at the determination of the relative importance of patient-relevant decision criteria as well as to compare two methods of measuring preference. In total, seven therapy-related attributes (three levels each) were tested. The sample contained patients receiving oral anti-diabetics (OAD) (N=200) or insulin (N=188). **RESULTS:** The qualitative study identified 22 patient-relevant treatment-characteristics. Out of these the seven most important were included in AHP and BWS. The AHP- as well as BWS-surveys resulted in a dominance of the attribute "HbA1c-Level", for both OAD- and Insulin-patients. In the OAD-group AHP and BWS independently showed the same ranking of the three attributes: "Delay of Insulin-Therapy" (Rank 2), "Occurrence of hypoglycemia" (Rank 3) and "Weight changes" (Rank 4). In the Insulin-group "Occurrence of hypoglycemia" was ranked second using AHP and third within BWS. "Weight changes" were ranked equally in both methods. However their relevance among different patient groups changed. **CONCLUSIONS:** In both patient-groups AHP and BWS show similar results. Nonetheless both groups have different horizons of experience and differ in the ranking of decision criteria. For the first time the methods of AHP and BWS were used to assess patients' preferences for different characteristics of treatment in Type-II-Diabetes, as well as the influence of those criteria on the patient benefit.

PDB87

THE DIABETIC PERIPHERAL NEUROPATHIC PAIN IMPACT (DPNPI) MEASURE – PSYCHOMETRIC VALIDATION OF A NEW PATIENT REPORTED OUTCOME MEASURE

Brod M[1], Ramasamy A[2], Bushnell DM[3], Blum SI[2]
[1]*The Brod Group, Mill Valley, CA, USA,* [2]*Forest Research Institute, Jersey City, NJ, USA,* [3]*Health Research Associates, Inc., Seattle, WA, USA*

OBJECTIVES: The Diabetic Peripheral Neuropathic Pain Impact (DPNPI) Measure is a patient-reported outcome (PRO) measure developed in accordance with the FDA PRO guidance for assessing the impacts of living with Diabetic Peripheral Neuropathic Pain (DPNP). A validation study was conducted to evaluate the measurement model and properties of the 27-item draft version of the DPNPI. **METHODS:** A non-interventional, observational, survey-based validation study enrolled outpatients from clinical sites in the United States. Recruitment included diagnosed DPNP patients (aged 18-80) both treated and untreated with prescription agents. Subjects completed a retest survey via mail two weeks after their in-clinic assessment. Analyses included assessment of the measurement model (factor analysis), reliability (internal consistency, test-retest) and validity (content, known-groups) of the DPNPI. IRT was utilized to evaluate item fit and function. **RESULTS:** Out of 124 subjects (56% male, mean age 62.8),105 completed the retest survey. Nine items from the draft version were deleted due to conceptual issues and/or redundancy. Factor analysis confirmed the three hypothesized domains: *Physical/Mobility Function*; *Daily Life*; *Sleep*. All domains and the total score were internally consistent (0.91 to 0.96) and reproducible (0.84 to 0.91). All *a priori* convergent validity hypotheses were confirmed ($p<.001$) with moderate-strong association between the total and/or subscale scores on the DPNPI measure and other logically related measures (range 0.43 to 0.79). Additionally, all *a priori* hypothesized associations for content and known-group validity of domains and total score were confirmed ($p<.001$) and IRT fit statistics were within acceptable range. **CONCLUSIONS:** The final 18-item version of the DPNPI can be considered a well-designed, valid and reliable measure of the impact of DPNP on patients' daily lives and physical functioning. This measure can be used as an endpoint in clinical trials to assess impacts related to DPNP. Further study is needed to understand the responsiveness of the DPNPI.

PDB88

HOW HYPOGLYCEMIA IMPACTS QUALITY OF LIFE AND TREATMENT SATISFACTION IN TYPE 2 DIABETES MELLITUS PATIENTS ON BASAL-BOLUS INSULIN THERAPY?

Ionova TI[1], Odin VI[2], Nikitina TP[1], Kurbatova KA[1], Shablovskaya NE[1]
[1]*Multinational Center for Quality of Life Research, Saint-Petersburg, Russia,* [2]*Military Medical Academy, Saint-Petersburg, Russia*

OBJECTIVES: Hypoglycemia burden is the most common problem in patients with type 2 diabetes mellitus (T2DM) receiving insulin treatment. However, how hypoglycemia affects quality of life (QoL) and treatment satisfaction in this patient population is less clear. We aimed to study the QoL and treatment satisfaction in T2DM patients on basal-bolus insulin therapy with the absence and presence of different types of hypoglycemia. **METHODS:** A total of 500 T2DM patients receiving basal-bolus insulin therapy for at least 6 months were enrolled in the survey: male/female 122/378; mean (SD) age 61.8 (8.4) yrs; mean (SD) time from T2DM diagnosis 12.8 (6.9) yrs. Mean HbA1c level was 8.3%. Patients were classified as with no, non-severe, severe and nocturnal hypoglycemia events during the last month. Patients filled out SF-36 and Patient Treatment Satisfaction Questionnaire. The impact of hypoglycemia on QoL and treatment satisfaction was examined through multivariate regression, adjusting for sociodemographics and disease status. QoL and treatment satisfaction scores were analyzed using t-test, ANOVA, Chi-square test. **RESULTS:** After adjustment, QoL and treatment satisfaction decreased with the increase of hypoglycemia events ($p<0.05$). Patients with hypoglycemia had significantly lower QoL scores for 6 out of 8 SF-36 scales as compared to those without hypoglycemia ($p<0.05$). Treatment satisfaction was higher in patients without hypoglycemia than in those with hypoglycemia (mean score 7.25 vs 8.0; $p=0.01$). Patients with nocturnal and severe hypoglycemia had significant reduction of role-physical, social functioning, vitality and pain as compared to patients with non-severe hypoglycemia ($p<0.05$). The percentage of patients who were completely dissatisfied or poorly satisfied with treatment was higher in the group with severe or/and nocturnal hypoglycemia than in those with non-severe hypoglycemia (20% vs 8%; $p=0.002$). **CONCLUSIONS:** Hypoglycemia has negative impact on QoL and treatment satisfaction in T2DM patients. Severe and nocturnal hypoglycemia significantly decreases QoL and reduces treatment satisfaction.

PDB89

ASSESSING QUALITY OF LIFE IN ADULT GROWTH HORMONE DEFICIENCY: FURTHER DEVELOPMENT OF THE QOL-AGHDA

Graham JE, McKenna S, Wilburn J, Twiss J
Galen Research Ltd., Manchester, UK

OBJECTIVES: The QoL-AGHDA assesses quality of life (QoL) specific to adults with Growth Hormone Deficiency (GHD). Questionnaire content was derived from qualitative interviews conducted with individuals who had the condition. Since its development a number of new language adaptations have been made for Europe (9), Eastern Europe (4), and Central and South America (2). New language versions of the measure were required for use in two major new multinational clinical trials. These were for Greece, Hungary, Israel, Romania, Russia, Slovakia, Ukraine and the US (Spanish). **METHODS:** The dual-panel methodology was employed to translate each of these measures. This approach has been used in the adaptation of all needs-based QoL measures. Two panels are held. The first employs local people who are also proficient in English who agree the most appropriate translation for the instructions and items. The second panel involves lay people who ensure that the level of language is appropriate and will be understood by future respondents. Following translation, cognitive debriefing interviews were conducted with adults with GHD in each country. **RESULTS:** No major difficulties were experienced in producing